

# Industry-Funded Research and Conflict of Interest: An Analysis of Research Sponsored by the Tobacco Industry through the Center for Indoor Air Research

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**Abstract** The Center for Indoor Air Research (CIAR) was created by three United States tobacco companies in 1988. Its stated mission is to fund high-quality, objective research related to indoor air, including studies of environmental tobacco smoke (ETS). Because CIAR is financed by the tobacco industry and funds research related to tobacco, it fosters an inherent conflict of interest. We consider whether this conflict of interest has affected the content, quality, or use of research funded by CIAR. We hypothesize that the tobacco industry might be using CIAR to develop scientific data to support its position that ETS is not harmful to health. CIAR funds two types of projects: "Peer-reviewed" projects are awarded after peer review by a group of scientists, whereas "special-reviewed" projects are awarded directly by tobacco industry executives. CIAR's special-reviewed projects are more likely than its peer-reviewed projects to be related to ETS, to support the tobacco industry position, and to be used by the industry to argue that smoking should not be regulated in public places. Our findings suggest that the tobacco industry is funding special-reviewed projects through CIAR to develop scientific data that it can use in legislative and legal settings. The industry may be financing peer-reviewed projects through CIAR to enhance its credibility, to provide good publicity, and to divert attention from ETS as an indoor air pollutant. CIAR's stated mission of funding high-quality, objective research has been compromised by conflict of interest, and at least some of CIAR's projects are being used to promote the tobacco industry's agenda.

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Scientific evidence now strongly suggests that exposure to environmental tobacco smoke (ETS) is harmful to the health of persons who do not smoke. Studies have shown that passive smoking can cause lung cancer (Hirayama 1981; Fontham et al. 1994) and heart disease (Glantz and Parmley 1991; Steenland 1992) in adults and that it increases the risk for sudden infant death syndrome (DiFranza and Lew 1995) and various respiratory disorders in children (U.S. Environmental Protection Agency 1992). In 1986, two scientific consensus reports on the harmful effects of exposure to ETS were published independently by the National Academy of Sciences (1986) and by the U.S. Surgeon General (U.S. Department of Health and Human Services 1986). And in 1992, the U.S. Environmental Protection Agency classified ETS as a known Group A human carcinogen (U.S. Environmental Protection Agency 1992). The growing awareness of the harmful effects of passive smoking has led to increased restrictions on smoking in public places to protect nonsmokers from exposure to ETS.

In contrast, a study published in 1992 in a peer-reviewed journal concluded that "acceptable air quality can be maintained [indoors] with moderate amounts of smoking" (Turner et al. 1992: 19). This study was funded by the Center for Indoor Air Research (CIAR), which was created by U.S. tobacco companies in 1988. CIAR's stated mission is to fund high-quality, objective research related to indoor air, including studies of ETS. Both CIAR and the tobacco industry maintain that CIAR is an independent organization. In particular, they emphasize that CIAR's projects are funded in a "scientifically rigorous and objective manner" based on peer review by a group of independent scientists and that this peer review process "ensures that only high quality research . . . is recommended for funding" (Center for Indoor Air Research 1994: 3).

Whenever an industry funds research that is directly related to its product, there is concern that conflict of interest may influence the research in some way (Bond 1991; Hillman et al. 1991; Blank 1992; Rothman 1993; Chren 1994; Witt and Gostin 1994). In particular, the sponsor might apply overt or covert pressure on the investigator to produce results that will be favorable (Hillman et al. 1991). For example, the sponsor could recommend that the investigator use a study design that would be more likely to favor its product. Or the sponsor could encourage a researcher to emphasize certain conclusions in the final publication of the data. Even without any external pressure, investigators may feel consciously or subconsciously compelled to publish findings that are pleasing, or at least not damaging, to their sponsors (Hillman et al. 1991).

In particular, investigators may fear that future funding will be denied if they publish unfavorable data (Hillman et al. 1991).

Several studies on the effects of industry sponsorship indicate that these concerns about conflict of interest are justified. One showed that research funded by the chemical industry is more likely than government-funded research to conclude that occupational exposure to chemical agents is not harmful (Swaen and Meijers 1988). Another study found that research sponsored by the pharmaceutical industry is more likely than research funded through other sources to favor the new drug being evaluated (Davidson 1986). Similarly, a third study showed that research sponsored by pharmaceutical companies almost always concludes that the sponsor's drug is equivalent or superior to comparison drugs, even when the data do not completely support this conclusion (Rochon et al. 1994). These studies provide compelling evidence that industry funding may influence the type of research conducted and the conclusions drawn from the data.

History has also shown that, when scientific findings are particularly damaging, industry may try to conceal, manipulate, or deny the findings. The asbestos industry, for example, funded external contract research on the health effects of asbestos from the 1930s to the 1950s (Lilienfeld 1991). According to internal memos, these studies suggested that exposure to asbestos could cause asbestosis and lung cancer. However, the study results were suppressed, and the industry denied that asbestos was hazardous to health (Lilienfeld 1991). Similarly, the lead industry has denied or minimized evidence suggesting that lead in paint is a common cause of disease in children (Rabin 1989).

The tobacco industry has a history of financing scientific research that it claims is independent but is actually designed to fulfill the industry's needs (Bero et al. 1995). In 1954, U.S. tobacco companies created the Tobacco Industry Research Committee, which was later renamed the Council for Tobacco Research-U.S.A., Inc. The industry stated publicly that the council's purpose was to fund independent scientific research on the health effects of smoking and that, to ensure the objectivity of the research, projects would be selected based on peer review by an independent science advisory board (Council for Tobacco Research 1992). However, internal tobacco industry documents reveal the existence of a "special projects" division within the Council for Tobacco Research (Freedman and Cohen 1993; Bero et al. 1995). Special projects were funded based on the recommendations of tobacco industry lawyers, rather than the science advisory board, and were not peer reviewed

before funding. The primary purpose of special projects, according to tobacco industry lawyers, was to develop scientific data that could be used to defend tobacco companies against litigation (Sarokin 1988; Bero et al. 1995). In addition, the special projects allowed the industry to cultivate relationships with scientists who could later be called on to testify on the industry's behalf (Bero et al. 1995). The Council for Tobacco Research's special projects were often designed specifically to divert attention from tobacco as a cause of disease (Bero et al. 1995). For example, studies were funded to show that poor nutrition, occupation, or genetic predisposition could cause the same diseases attributed to smoking. In addition, the study designs of the special projects were sometimes altered so they would be more likely to produce results that would support the tobacco industry position (Bero et al. 1995).

Given general evidence suggesting that industry sponsorship can influence the results or conclusions of sponsored research and specific evidence of previous efforts by the tobacco industry to control the direction of the research it funds, we hypothesized that research funded by CIAR might be affected by conflict of interest. The tobacco industry argues that exposure to ETS is too minimal to cause any real damage, and that epidemiologic studies of passive smoking are flawed and do not prove that ETS is harmful (Tobacco Institute 1986). The industry has an obvious interest in producing scientific data to support these arguments, because policy makers and juries would be more likely to accept them if they were based on hard data. In fact, a confidential report prepared by the Roper Organization (1978: A7) for the Tobacco Institute noted that the industry's best strategy for countering public concern about passive smoking was to fund scientific research. The report stated: "The strategic and long run antidote to the passive smoking issue is, as we see it, developing and widely publicizing clear-cut, credible, medical evidence that passive smoking is not harmful to the non-smoker's health."

Thus the purpose of our study was to analyze the content, quality, and use of research funded by CIAR to determine whether it is funding truly independent research or whether it is financing studies that appear to be motivated by tobacco industry interests. We hypothesized that, although CIAR claims to be objective and independent, the tobacco industry might be funding research through CIAR to support its position that passive smoking has not been proved harmful to health.

### **CIAR's Peer-Reviewed and Special-Reviewed Projects**

CIAR has released several Request for Applications (RFAs) brochures that describe its organizational structure, mission, and funding process (Center for Indoor Air Research 1989, 1991, 1992a, 1994). According to these RFAs, CIAR is an independent, nonprofit corporation formed in 1988 (Center for Indoor Air Research 1994). It has three types of corporate members: charter, regular, and associate. Charter members are "those corporations that established the Center and are currently providing the majority of funding," whereas regular and associate members are "those persons or corporations that are interested in indoor air quality research but were not involved in the establishment of the Center" (Center for Indoor Air Research 1994: 3). Charter and regular members are represented on the board of directors but associate members are not (Center for Indoor Air Research 1994).

Although these types of memberships are clearly described in CIAR's RFAs, the names of the members are listed only in the appendix. CIAR's original charter members were Philip Morris U.S.A., R. J. Reynolds Tobacco Company, and Lorillard Corporation (Center for Indoor Air Research 1989); Svenska Tobaks A.B., a Swedish domestic tobacco company, was added to the list of charter members in 1994 (Center for Indoor Air Research 1994). CIAR has two regular members: Hoechst Celanese and Mead Paper; its associate members include several paper and packaging companies. Thus CIAR was created and is primarily financed by tobacco companies, and its board of directors is composed primarily of tobacco industry representatives.

CIAR's mission, as stated in its 1989-90 research agenda, is "to create a focal point organization of the highest scientific caliber to sponsor and foster quality, objective research in indoor air issues including environmental tobacco smoke, and to effectively communicate research findings to the broad scientific community" (Center for Indoor Air Research 1989: 1). This mission statement was modified in 1992 and no longer includes a specific reference to ETS (Center for Indoor Air Research 1992a). CIAR states that its mission is fulfilled primarily by funding scientific and technical research related to indoor air.

The peer-review process that CIAR uses to select projects for funding is described in its RFA brochures as follows:

*The research agenda of the Center for Indoor Air Research is formulated by the Science Advisory Board (SAB), a multi-disciplinary*

group of individuals with reputations for expertise and scientific leadership in the disciplines relevant to indoor air research. . . . After the SAB establishes the research agenda, the Center announces to the scientific community at large that research applications in response to the agenda are being accepted. The review of proposals and their selection for funding is accomplished in a scientifically rigorous and objective manner. Applications are reviewed first for scientific quality by the applicant's peers selected from the group listed in Appendix B [of the RFA]. The SAB, in turn, reviews the applications and peer evaluations, and develops recommendations on the selection of applications. Studies recommended by the SAB are subject to final approval by the Board of Directors. (Center for Indoor Air Research 1994: 3)

The RFAs also state that investigators funded by CIAR are encouraged to publish their findings in the peer-reviewed literature (Center for Indoor Air Research 1994). CIAR's review process is similar to the grant-approval processes used by many foundations, although all of CIAR's projects are funded as contracts rather than as grants.

Although CIAR's publications state that its projects are funded through the peer-review process previously described, we found that some projects receive a special-review process. CIAR publishes a brochure that lists the projects it has funded to date (Center for Indoor Air Research 1992b). They are classified as "research," "applied," or "other," but the differences between these categories are not explained. Through interviews with CIAR staff members, we were informed that research projects are traditional scientific investigations funded through the peer-review process described in CIAR's publications; applied and other projects are more goal-oriented studies funded directly by the board of directors without receiving peer review (Marquardt 1993). As we noted, CIAR's board of directors consists primarily of representatives of the charter tobacco companies. None of CIAR's publications mention that some of its projects are awarded through a special-review process.

We tried to confirm the information about CIAR's special-review process by writing a letter to the executive director of CIAR, Max Eisenberg. We explained in detail our understanding of the special-review process used for applied and other projects and asked for confirmation or clarification of the process. In response, we received only a note stating "For your information," along with a packet of CIAR's informational brochures. However, one recipient of an applied project, Roger A. Jenkins (1995), of Oak Ridge National Laboratory, testified at length regard-

ing the funding process used for his project. He stated that CIAR had approached him with a proposal for the project, and that he and his colleagues had developed the study methodology with input from CIAR, R. J. Reynolds, and Bellomy Research (a marketing research firm). Therefore, we believe that the information we received by telephone interview, which characterized applied and other projects as being awarded by CIAR's board of directors without undergoing peer review, was accurate.

Because CIAR's applied and other projects receive a special-review process, and because we hypothesized that they might be similar to the Council for Tobacco Research's special projects, we refer to them collectively as "special-reviewed" projects throughout this article. We refer to CIAR's "research" projects as "peer-reviewed" projects. Based on information in CIAR's tax forms, which we obtained from the Internal Revenue Service, we determined that CIAR awarded \$11,209,388 for peer-reviewed projects and \$4,022,723 for special-reviewed projects from 1989 to 1993.<sup>1</sup>

For our analysis of the content, quality, and use of research funded by CIAR, we hypothesized that CIAR's special-reviewed projects would be more likely than its peer-reviewed projects to support the tobacco industry position, and that the results of special-reviewed studies would be used by the tobacco industry to lobby against regulation of smoking in public places.

### Content of Research Funded by CIAR

We conducted a content analysis of CIAR-funded research to determine what projects and which investigators are being funded. We were particularly interested in determining what percentage of CIAR-funded research is related to ETS. As we noted previously, research related to ETS has a high potential for being biased by conflict of interest, because the tobacco industry could use the results in legal and legislative settings.

CIAR provided information regarding projects it had funded from January 1988 to October 1993, including the title of each project, the name and affiliation of each principal investigator, the date the project was originally funded, and a one-paragraph description of the purpose of the project (Center for Indoor Air Research 1992b, 1993a). Based on the description, we classified the topic of each project as *ETS related* if it

1. Figures do not include awards made in 1990 because tax forms were not available from the Internal Revenue Service.

studied an aspect of tobacco, tobacco smoke, or a tobacco-specific substance such as nicotine; or as *non-ETS related* if it studied general indoor air quality and did not specifically mention tobacco.

Then we subclassified the topics of the projects into the categories of health effects, exposure, or other. A *health effects* study evaluated the effects of exposure to a substance, including studies conducted in cells, animals, or humans. An *exposure* study measured exposure to a substance but did not evaluate the effects of that exposure; these included studies of exposure markers such as cotinine (a nicotine metabolite). Studies that did not evaluate either health effects or exposure were classified in the *other* category. One project, for example, studied whether tobacco smoke is perceived primarily through sight or smell.

Table 1 summarizes our findings on the topics of projects funded by CIAR. Almost two-thirds of CIAR's special-reviewed projects were related to ETS, compared with 30 percent of its peer-reviewed projects. In addition, most special-reviewed projects studied exposure, rather than health effects. These findings suggest that research related to ETS, particularly exposure research, is a high priority for the tobacco industry executives who select CIAR's special-reviewed projects. One of the tobacco industry's main arguments regarding passive smoking is that persons are not exposed to sufficient levels of ETS to cause any serious damage (Tobacco Institute 1986). It is therefore possible that the tobacco industry is funding research through CIAR's special-reviewed projects to develop data it can use to support this claim. In addition, from a legal perspective, a study measuring exposure to ETS would be much less damaging to the industry than one showing that ETS causes disease; thus it is "safer" for the industry to sponsor exposure research.

We also examined the affiliations of CIAR-funded principal investigators (PIs). Based on the information provided by CIAR, we coded the affiliation of each PI as either academic, private sector, or other. They were classified as academic if their stated affiliation was a university or college and as private sector if they were affiliated with a private-sector business, consulting firm, or contracting agency. All other affiliations were classified as other. None of the PIs had more than one affiliation listed.

Table 2 summarizes our findings regarding the affiliations of CIAR-funded PIs. Nearly all of the PIs on peer-reviewed projects had academic affiliations, whereas almost 40 percent of the PIs on special-reviewed projects were affiliated with private-sector organizations. Two special-reviewed projects were awarded to the president of Healthy Buildings



**Table 1** Topics of Projects Funded by CIAR, 1988 to 1993

Topic	Number of Peer-Reviewed Projects (n = 40)	Number of Special-Reviewed Projects (n = 19)
ETS Health Effects	6	2
ETS Exposure	6	8
Other ETS	0	2
Total ETS	12 (30%)	12 (63%)
Non-ETS Health Effects	14	0
Non-ETS Exposure	13	6
Other Non-ETS	1	1
Total Non-ETS	28 (70%)	7 (37%)

Comparison of total ETS vs. total non-ETS for peer-reviewed vs. special-reviewed projects: Fisher's Exact Test,  $p = .02$ .

**Table 2** Affiliations of Principal Investigators (PIs) funded by CIAR<sup>a</sup>

Affiliation	Percentage of PIs on Peer-Reviewed Projects (n = 34)	Percentage of PIs on Special-Reviewed Projects (n = 18)
Academic	94	56
Private Sector	3	39
Other	3	6

Chi square = 12.26, df = 2,  $p = 0.002$ .

<sup>a</sup>Two PIs received funding for both peer-reviewed projects and special-reviewed projects. They were classified as PIs on special-reviewed projects throughout our analyses. However, our results would not have been different if we had classified them as PIs on peer-reviewed projects, or if we had placed them in a separate category.

International (HBI), Gray Robertson, a long-time tobacco industry consultant who has testified frequently on the industry's behalf (Levin 1993; U.S. House 1994a). It is therefore possible that special-reviewed projects tend to be awarded to PIs in the private sector because some of them may be sympathetic to the tobacco industry position. Alternatively, academic investigators may be wary of accepting funding for special-reviewed projects because they have not been subject to a formal peer-review process.

We also found that three of CIAR's special-reviewed projects were awarded to PIs who are currently members of CIAR's science advisory board. This sort of financial relationship between the advisory board and the tobacco industry could raise concern about the board's ultimate inde-

pendence. It also suggests that the industry may reward some members of the science advisory board by providing funding for their projects.

### Quality of Research Funded by CIAR

The next phase of our study was an evaluation of the quality of research funded through CIAR. We could not directly evaluate the quality of the projects themselves, because we did not have access to the proposals submitted to CIAR. As a surrogate, we evaluated the quality of publications that have resulted from CIAR-funded research.

We identified articles that had resulted from CIAR-funded research by contacting CIAR and by searching MEDLINE and Current Contents for articles coauthored by CIAR-funded PIs. CIAR provided two lists that collectively identified sixty-one publications that had resulted from its funded projects (Center for Indoor Air Research 1993b, 1993c). Ten more articles that acknowledged CIAR as a source of funding were identified through MEDLINE and Current Contents, giving us a total of seventy-one possible articles for inclusion. Eleven of these articles (15 percent) were not contained within any of the University of California, California State, or Stanford University libraries and therefore were not available through our interlibrary loan system. We obtained five of these articles by contacting the authors; another four were institutional reports, which we purchased. We could not obtain two articles (3 percent), both of which were published in symposia and had been coauthored by a PI on a special-reviewed project (Hedge 1991; Hedge et al. 1992). Therefore we assessed the quality of sixty-nine articles that resulted from CIAR-funded research based on the criteria described in the next section.

Several studies identified various factors that are associated with publication quality. For example, peer-reviewed publications have been associated with higher quality (Barnes and Bero, unpublished data; Rochon 1994) and a more balanced presentation of information (Bero et al. 1992) compared with non-peer-reviewed publications. Similarly, articles published in symposia, which typically are not peer reviewed, have been associated with poor quality and unbalanced findings (Bero et al. 1992, 1994; Rochon 1994). In addition, review articles generally have been associated with biases based on the affiliations of the reviewers (Chalmers et al. 1990). Studies have also shown that publications based on industry-funded research tend to draw pro-industry conclusions (Davidson 1986; Swaen and Meijers 1988; Lexchin 1993; Rochon et al. 1994; Cho and Bero forthcoming).

To assess factors associated with publication quality, we coded the peer-review status, type of publication, and source(s) of funding acknowledged for the articles that resulted from CIAR-funded projects. An article was coded as peer reviewed if the journal in which it had been published stated it was peer reviewed, published a list of reviewers, or required manuscripts to be submitted for review before publication; otherwise, it was coded as non-peer reviewed. Type of publication was coded as symposium article, original research article, review, or other based on how the article was described in the table of contents. All articles published in symposia were classified as symposium articles, regardless of whether they were original research articles or reviews. Source(s) of funding acknowledged were coded as tobacco if the stated sponsor(s) was a tobacco company, the Tobacco Institute, CIAR, or the Council for Tobacco Research; as multiple if both CIAR and a nontobacco source of funding were acknowledged; as other if an organization other than CIAR was acknowledged; and as none if no source of funding was acknowledged.

We also evaluated the conclusions of the articles to determine whether those resulting from CIAR-funded research tend to support the tobacco industry position that ETS is not harmful to health. An article was classified as pro-industry if it concluded that there is no evidence that ETS is associated with adverse health effects, that the evidence is inconclusive, that confounding variables are responsible for health effects attributed to ETS, that studies on ETS are statistically flawed, or that the level of exposure to ETS is not high enough to cause health problems. In addition, articles that made policy recommendations consistent with tobacco industry proposals, such as accommodating both smokers and nonsmokers in restaurants or workplaces, were classified as pro-industry. An article was considered neutral if it did not discuss the health effects of ETS. An article was considered anti-industry if it concluded that ETS is associated with adverse health effects or if it made policy recommendations consistent with tobacco-control efforts. These categories have been used previously (Bero and Glantz 1993; Bero et al. 1994) and are based on the written statements of the tobacco industry (Tobacco Institute 1986).

High-quality publications were considered those that were published in peer-reviewed journals, those that presented original research findings and had not been published in symposia, and those that acknowledged a source of funding other than the tobacco industry. We used the chi-square statistic to test the hypothesis that articles resulting from peer-reviewed projects would be more likely than articles resulting from special-reviewed projects to be associated with these high-quality characteristics.

We also analyzed the stated conclusions of the articles to determine whether articles resulting from special-reviewed projects would be more likely than those resulting from peer-reviewed projects to be pro-industry.

Table 3 summarizes our findings regarding the quality and conclusions of CIAR's project-related publications. As hypothesized, articles resulting from special-reviewed projects tended to be associated with poor-quality characteristics. Almost one-half of articles resulting from special-reviewed projects were published in non-peer-reviewed journals. In addition, 30 percent were published in symposia and 20 percent were published as book sections, institutional reports, and other types of publications. Finally, articles associated with CIAR's special-reviewed projects tended to acknowledge the tobacco industry as the sole source of funding.

Table 3 also shows that articles based on CIAR's special-reviewed projects were more likely than articles from its peer-reviewed projects to support the tobacco industry position. These findings support evidence from previous studies suggesting that industry funding is associated with pro-industry outcomes (Davidson 1986; Swaen and Meijers 1988; Lexchin 1993; Rochon et al. 1994). In addition, these findings provide further support for our hypothesis that the tobacco industry may be funding research through CIAR's special-reviewed projects to produce data that are favorable to its position.

#### Use of CIAR-Funded Research

The final phase of our study was an analysis of the use of research funded by CIAR. We hypothesized that, although CIAR-funded research has led to publications both supporting and opposing the tobacco industry position, the industry would selectively cite the studies that support its claims. In addition, we hypothesized that PIs on special-reviewed projects would be more likely than PIs on peer-reviewed projects to have testified on the industry's behalf. To determine how CIAR-funded research was being used, we analyzed testimony presented by CIAR-funded researchers at federal hearings related to ETS.

We used three sources to identify CIAR-funded researchers who have testified or submitted statements on issues related to ETS: the list of persons who testified before the Occupational Safety and Health Administration (OSHA) regarding its proposed indoor air quality standard (U.S. Department of Occupational Safety and Health Administration 1994); the list of persons who submitted technical comments to the U.S. Envi-

**Table 3** Quality and Outcomes of Publications Resulting from CIAR-Funded Research

	Percentage of Articles Resulting from Peer-Reviewed Projects (n = 48)	Percentage of Articles Resulting from Special-Reviewed Projects (n = 21)	Statistical Test
Peer-Review Status			
Peer Reviewed	81	52	Fischer's Exact,
Not Peer Reviewed	19	48	$p = 0.02$
Type of Article			
Symposium	17	33	Chi square = 4.37
Original	71	48	df = 3
Review	2	0	$p = 0.22$
Other	10	19	
Sources(s) of Funding Acknowledged			
Tobacco Industry	15	62	Chi square = 24.12
Multiple	79	19	df = 3
Other	2	0	$p < 0.0001$
None Stated	4	19	
Conclusion			
Pro-industry	2	29	Chi square = 11.89
Anti-industry	6	9	df = 2
Neutral	92	62	$p = 0.003$

ronmental Protection Agency regarding its draft risk assessment of ETS, which had been obtained for a previous study (Bero and Glantz 1993); and the tables of contents of congressional hearings related to ETS. We identified congressional hearings by searching the Congressional Information Services Index from 1970 to 1994 using the key words "smoking" and "tobacco." We included only those hearings that focused on ETS or proposals to restrict smoking in public places. We identified nine hearings, including three on proposals to restrict or ban smoking in federal buildings (U.S. Senate 1985; U.S. House 1986, 1993b), two on proposals to restrict smoking in public places nationwide (U.S. House 1993a, 1994b), two regarding proposals to ban smoking on airline flights (U.S. House 1987, 1989), one on the health effects of exposure to ETS (U.S. House 1978), and one involving a critical review of the U.S. Environmental Protection Agency's risk assessment of ETS (U.S. House 1993c).

We examined these sources to identify CIAR-funded researchers who had either testified orally or submitted written statements. When available, we read both written statements and transcripts of oral testimony to determine whether they discussed CIAR-funded research, whether the researcher's relationship with the tobacco industry was disclosed, and whether the testimony supported the tobacco industry position on ETS (as we previously defined for conclusions of articles).

We found that 28 percent (five of eighteen) of PIs on special-reviewed projects had submitted statements related to ETS, compared with 3 percent (one of thirty-four) of PIs on peer-reviewed projects (Fisher's exact test,  $p = .0154$ ). One PI on a special-reviewed project had testified on five separate occasions, whereas all others had testified only once.

All of the statements submitted by CIAR-funded PIs supported the tobacco industry position that ETS is not harmful to health. The PI who had testified five times consistently argued that smoking can be accommodated indoors through adequate ventilation; two PIs argued that evidence is insufficient to conclude that ETS causes disease; one maintained that there is a lack of biological plausibility to conclude that ETS is harmful, and that confounding variables could explain the statistical association between ETS and disease; one argued that ETS is not a major cause of sick building syndrome and poor air quality; and one argued that workplace exposure to ETS is very low (implying that the exposure is too minimal to cause disease).

Data from at least three of CIAR's special-reviewed projects have been presented at hearings related to ETS. Two special-reviewed projects were discussed at OSHA's hearings regarding its proposed indoor air quality standard, which recommends restricting or banning smoking in workplaces nationwide, whereas the third was discussed at hearings related to banning smoking on commercial airline flights. In all three cases, the data from CIAR's special-reviewed projects were used to support the tobacco industry position.

One of the OSHA statements was submitted by Roger A. Jenkins, who discussed preliminary data from a special-reviewed project entitled "Determination of Human Exposure to Environmental Tobacco Smoke." According to CIAR's tax records, Oak Ridge National Laboratory received \$797,892 in 1993 to conduct this study. Jenkins disclosed in his statement that the project had been funded by CIAR; however, he stated orally that he was not appearing as an advocate for or against OSHA's proposed standard, but "as a scientist that's been conducting a study and

gathering some information I think is going to be useful to OSHA" (Jenkins 1995: 9690).

Jenkins testified orally that the purpose of the study was to measure exposure to ETS in the workplace, and to compare the levels of workplace and non-workplace exposure. He stated that three organizations had participated in the study: Bellomy Research, a marketing research firm based in Winston-Salem, North Carolina, had recruited the study participants; R. J. Reynolds had conducted the laboratory analyses to determine the levels of exposure to ETS in the various groups; and Oak Ridge National Laboratory was responsible for approving the overall study design and for analyzing and interpreting the data. Jenkins noted that Bellomy often conducts marketing research for R. J. Reynolds.

The study design Jenkins described contains several potential sources of bias. Specifically, it is highly unusual for firms with strong interests in the outcome of a study to be allowed to select the study participants and to conduct the laboratory analyses, particularly when other firms could have been hired. During his testimony, Jenkins stressed that several steps had been taken to ensure that R. J. Reynolds did not manipulate the data in any way. However, it is unlikely that peer reviewers would have approved a study design with such a high potential for bias.

Jenkins also noted that the demographics of the study group were slightly skewed. For example, the participants were more likely to be women, to have high socioeconomic status, to have high educational levels, to be white, and to work in white-collar occupations. It is possible that many or all of these factors would be associated with lower-than-normal workplace exposure to ETS.

According to Jenkins, the preliminary results from the study suggested that most persons are exposed to very little ETS on the job. This conclusion supports the tobacco industry position that the federal government should not regulate smoking in the workplace.

The second CIAR special-reviewed project presented before OSHA was conducted by Alan Hedge, of the Department of Design and Environmental Analysis at Cornell University. According to CIAR's tax forms, Hedge received \$431,177 from 1989 to 1993 to conduct this project,<sup>2</sup> which studied the effects of different smoking policies and ventilation conditions on indoor air quality in office buildings (Center for Indoor Air

2. This figure does not include the amount of funding awarded in 1990 because tax forms were not available from the Internal Revenue Service.

Research 1992b). Hedge's oral testimony was not available for our analysis. However, in his written statement, Hedge (1994: 2) noted that his research showed "environmental tobacco smoke plays a very minor role, if any, in eliciting sick building syndrome complaints." In addition, he stated that OSHA's proposal to require separate ventilation systems in offices that allow smoking was "unnecessarily restrictive" (Hedge 1994: 3). Thus his statement also supports the tobacco industry position that OSHA should not regulate smoking in the workplace.

A third CIAR special-reviewed project was discussed at a congressional hearing related to banning smoking on commercial aircraft (U.S. House 1989). This study was conducted by Torbjorn Malmfors, of Malmfors Consulting Inc., and it measured levels of ETS on aircraft. Larry C. Holcomb, of Holcomb Environmental Services, presented preliminary findings of the study and stated that he acted as a consultant to CIAR on the project. Holcomb also noted that he had been asked to submit his statement by the Tobacco Institute. According to Holcomb, "the results of the CIAR study confirm that ETS levels in general are very low in passenger cabins" (U.S. House 1989: 369). The study was later published in a peer-reviewed journal, and it concluded that exposure to ETS on aircraft is probably not responsible for health problems in either passengers or flight attendants (Malmfors et al. 1989).

These findings strongly suggest that the tobacco industry is funding research through CIAR to develop scientific data that it can use in legislative forums to support its position.

Concern regarding the quality of data resulting from CIAR special-reviewed projects has also been raised (U.S. House 1994a; Barnes et al. 1995). A congressional subcommittee recently concluded that 25 percent of the data from one of CIAR's special-reviewed projects may have been falsified or fabricated (U.S. House 1994a). The study was conducted by Gray Robertson, of HBI, and it involved an analysis of indoor air quality, including measures of ETS, in 585 office buildings. The study was published in a peer-reviewed journal (Turner et al. 1992) and reported that ETS levels in rooms used for "light" smoking were similar to levels in nonsmoking rooms. The article concluded that "with good ventilation, acceptable air quality can be maintained with moderate amounts of smoking" (Turner et al. 1992: 19).

The U.S. Congress's Subcommittee on Health and the Environment (U.S. House 1994a) conducted an investigation of the HBI study in which it obtained that company's raw data and compared them with data submitted in an interim report to CIAR. The subcommittee's analysis showed



Research 1992b). Hedge's oral testimony was not available for our analysis. However, in his written statement, Hedge (1994: 2) noted that his research showed "environmental tobacco smoke plays a very minor role, if any, in eliciting sick building syndrome complaints." In addition, he stated that OSHA's proposal to require separate ventilation systems in offices that allow smoking was "unnecessarily restrictive" (Hedge 1994: 3). Thus his statement also supports the tobacco industry position that OSHA should not regulate smoking in the workplace.

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that measures of respirable suspended particulates, which are used to estimate ETS levels, were substantially altered more than 25 percent of the time. Several other discrepancies were identified that would have tended to decrease the levels of ETS measured in rooms used for smoking (U.S. House 1994a). HBI employees confirmed that their data collection forms were routinely changed to minimize measurements of ETS. The subcommittee requested an independent analysis of HBI's data, which concluded that "the data [are] so marred by unsubstantiated data entries, discrepancies, and misclassifications that it raises serious questions of scientific fraud" (U.S. House 1994a: 6). Robertson has denied the congressional findings (U.S. House 1994a; Fry 1995).

According to information submitted to the subcommittee by the Tobacco Institute, representatives of HBI have testified at least 129 times before federal, state, or local government agencies on issues related to ETS. In our analysis, Robertson submitted a total of five statements, and he typically argued that smoking could be accommodated indoors through adequate ventilation.

Our findings on the use of CIAR-funded research provide further evidence to support our hypothesis that the tobacco industry is using CIAR's special-reviewed projects to produce data it can use in legislative and legal settings. In addition, our findings suggest that the industry may be using CIAR to develop relationships with researchers who might be willing to testify on behalf of the tobacco industry.

## Discussion

Together our findings suggest that CIAR is funding two types of projects for two different purposes. Peer-reviewed projects are funded based on the recommendations of independent scientists. They are awarded primarily to academic investigators and most of them are not related to ETS. Special-reviewed projects, on the other hand, are awarded based on the recommendations of tobacco industry executives. They are more likely than peer-reviewed projects to be related to ETS, to be awarded to private sector consultants, and to support the tobacco industry position that ETS has not been proved harmful to health. In addition, data from several of CIAR's special-reviewed projects have been presented at hearings related to ETS to support the tobacco industry agenda.

These findings suggest that CIAR's peer-reviewed and special-reviewed projects may be serving different purposes. The tobacco industry appears to be funding special-reviewed projects to develop scientific data that it

can use to influence policy. The motivation behind CIAR's peer-reviewed projects is less clear. It is possible that the industry is using them to deflect attention away from ETS as an indoor air pollutant, because most of them are not related to ETS. In addition, it is possible that peer-reviewed projects are being funded to gain good publicity and improve the industry's credibility.

### Influencing Policy

Our analysis of the use of CIAR-funded research suggests that the tobacco industry is using CIAR to develop scientific data it can cite in legislative settings to influence policy related to ETS. For example, data from two of CIAR's special-reviewed projects were presented at OSHA hearings on its proposed indoor air quality standard, and data from a third special-reviewed project were presented at a congressional hearing related to the proposed ban on smoking on commercial aircraft. In all three cases, these data were used to support the tobacco industry position that smoking should not be regulated.

Although the tobacco industry appears to be funding research through CIAR's special-reviewed projects in an attempt to influence policy on ETS, the impact of this strategy may be minimized by the lack of peer review associated with these projects. For example, the Oak Ridge National Laboratory study shows how lack of peer review appears to have led to a poor study design with a high potential for bias. Participants were selected for the study by a marketing research firm with ties to the industry, and laboratory tests were conducted by scientists employed by R. J. Reynolds. Given these sorts of compromises in study design, policy makers may be unwilling to accept the conclusions of the study, which support the tobacco industry position that workplace smoking should not be regulated.

In addition, the congressional subcommittee report on the HBI study suggests that data from one of CIAR's special-reviewed projects appear to have been dramatically altered. It is not clear from the subcommittee report whether HBI acted independently or with the approval of its tobacco-industry sponsors. However, it is likely that policy makers will examine testimony and research results presented by HBI with a particularly critical eye in the future.

### Deflecting Attention from ETS

Our study leaves unresolved the question of why the tobacco industry is funding peer-reviewed projects through CIAR. One possibility is that peer-reviewed projects are being used to deflect attention away from ETS as an indoor air pollutant, because more than two-thirds of CIAR's peer-reviewed projects study substances unrelated to tobacco. This hypothesis is supported by a document that was obtained as part of the congressional subcommittee inquiry into HBI. The document, which was circulated within HBI in late 1991 or 1992, stated that "the key objective of the HBI concept is to broaden the debate on indoor air quality to deflect the ETS challenge" (U.S. House 1994a: 5). In particular, HBI was to promote the belief that ETS is "a minor contributor" to indoor air problems.

The tobacco industry may also be trying to divert attention from ETS by funding projects it believes will support its position that ETS is not a health hazard, and by denying funds to projects that find that ETS is harmful. For example, one PI, who had received financing for a peer-reviewed project through CIAR, stated that his funding was not renewed after his study found that roosters exposed to ETS had larger atherosclerotic plaques than did unexposed roosters (Stolberg 1994).

The tobacco industry's power to deflect attention from ETS is dramatically increased by the fact that, to our knowledge, no other nationally based organization is funding research on ETS.

### Good Publicity

The tobacco industry may also be funding peer-reviewed projects through CIAR to provide it with good publicity and to enhance its credibility. The tobacco industry often cites its funding of independent research to improve its public image. For example, a publication produced by the Tobacco Institute entitled *Three Decades of Initiatives by a Responsible Cigarette Industry*, states:

Industry support of independent research exceeds \$162 million through 1988 and has resulted in publication of more than 3,000 scientific papers. . . . Pursuing its effort to advance scientific knowledge, tobacco industry support led to establishment of the Center for Indoor Air Research to award funds to independent investigators in the field of air quality in enclosed spaces. (Tobacco Institute, circa 1988)

In addition, the industry often uses the fact that it funds research to argue that "more research is needed." For example, a 1978 tobacco industry memo stated, "It is extremely important that the industry continue to spend their dollars on research to show that we don't agree that the case against smoking is closed" (Bloch 1994).

The tobacco industry may be using CIAR's peer-reviewed projects to enhance CIAR's credibility, so that the results of its special-reviewed projects will be more likely to be accepted. The industry has little to lose by funding peer-reviewed projects through CIAR, because most of them are not related to ETS.

### Implications for Industry Funding in General

Whenever an industry funds scientific research that will directly affect its business, a conflict of interest arises. This conflict occurs because the researcher has a responsibility to conduct methodologically sound, unbiased research and to disseminate the findings, regardless of how those findings might affect the industry. The industry, on the other hand, has a responsibility to maximize its profits, and its money is best spent on research that produces favorable data.

As many authors have noted, industry sponsorship can overtly or covertly influence the conduct and publication of research in various ways (Hillman et al. 1991; Blank 1992; Chren 1994; Witt and Gostin 1994). Industry may be more likely to fund research studies that it believes will produce desirable data. In addition, investigators may consciously or unconsciously design their research studies or present their findings in a way that is likely to be favorable to their sponsors. Investigators who rely heavily on industry funding may be particularly susceptible to industry pressure (Hillman et al. 1991).

Several authors have suggested that guidelines should be imposed to minimize the potential for bias in industry-funded research (Hillman et al. 1991; Blank 1992; Chren 1994; Witt and Gostin 1994). Chren (1994) has proposed that industry-funded research should be awarded through an independent third party to minimize contact between industry and investigators. In addition, Chren suggested that all industry-funded research should be awarded through contracts, rather than grants, which should specifically state that investigators will retain complete scientific freedom regarding study design, data analysis, and publication of findings.

CIAR fulfills the criteria proposed by Chren. It is a nonprofit corporation that acts as an intermediary between investigators and the tobacco

industry. In addition, all of CIAR's projects are funded through contracts, rather than grants, and CIAR's RFAs explicitly state that funded investigators are encouraged to publish their findings in peer-reviewed journals. CIAR has also taken additional steps to minimize the role of its sponsors in the funding process. In particular, it has given the primary responsibility of project selection to an independent group of scientists who serve on its science advisory board. Our analysis suggests that the projects funded through peer review by the advisory board are of high quality and have not been unduly influenced by conflict of interest.

However, our analysis also suggests that Chren's proposal does not necessarily minimize conflict of interest in industry-sponsored research. In particular, we found that the tobacco industry developed a system for circumventing CIAR's peer-review process to fund projects that would serve its needs. The studies funded through CIAR's special-reviewed projects appear to be those that had the highest potential to produce data that could be either harmful or beneficial to the industry, because most of them were related to ETS. It seems likely that the tobacco industry funded these studies through its special-review process to retain control of selection of the principal investigators and study design. If other industries were to create organizations similar to CIAR for funding external research, it seems possible that they might be similarly tempted to fund particularly sensitive studies through a special process.

### Implications for Disclosure

Our study raises several important issues related to disclosure. None of CIAR's publications disclosed that one-third of its projects are funded through a special-review process. In fact, CIAR's most recent publication of supported research no longer separates its projects into the categories of research, applied, and other (Center for Indoor Air Research 1995). If we had received this new brochure, we probably would not have thought to ask whether all of CIAR's projects are funded based on the peer-review process described in its publications. CIAR should clearly describe the funding process for its special-reviewed projects in all of its publications. In addition, special-reviewed projects should be clearly labeled in its publications to indicate that they were selected by tobacco industry executives rather than through a process of peer review.

Similar disclosure statements should be made in all publications resulting from CIAR-funded research. Journal editors and policy makers have increasingly called for researchers to disclose any potential conflicts

of interest, particularly financial ones (Relman 1984; Southgate 1987; International Committee of Medical Journal Editors 1988; Lundberg and Flanagin 1989; Relman 1990; Parish et al. 1991; Koshland 1992). We found that most CIAR-funded researchers disclosed CIAR as a source of funding in their publications and during their testimony on tobacco-related issues. However, as others have noted, there are varying degrees of disclosure (Rodwin 1989). CIAR-funded investigators tended simply to state that their research had been funded by the CIAR. However, most readers have never heard of CIAR and do not know that it is financed by the tobacco industry. Even in CIAR's RFAs, the fact that CIAR is supported by the tobacco industry is mentioned only in the appendix, on page 14 of a twenty-one-page pamphlet (Center for Indoor Air Research 1994).

An excellent example of full disclosure is provided by the Health Effects Institute. Publications that acknowledge the institute as a source of funding typically state that it is "an organization jointly funded by the U.S. Environmental Protection Agency and automotive manufacturers." An appropriate way for researchers to disclose funding from CIAR would be to state "This project was funded by the Center for Indoor Air Research (CIAR), an organization created and financed by tobacco companies." In addition, special-reviewed projects should further state "It was selected by tobacco industry representatives, rather than through a process of peer review." When the true nature of the funding process is disclosed in this way, the full potential for bias is made apparent.

### Implications for the Ethics of Accepting Tobacco Industry Funding

Finally, our findings support calls for investigators to refuse all tobacco industry financing. Many authors have argued that researchers should not accept funding of any sort from the tobacco industry (Taking Money from the Devil 1985; Wolinsky 1985; Bloch 1994; White, n.d.). In addition, James S. Todd (1994), executive vice-president of the American Medical Association, recently wrote to the deans of many U.S. medical schools and urged them not to accept support from the tobacco industry. The argument against taking tobacco industry money is that researchers will provide the industry with undeserved respectability, will be less likely to oppose the industry in other matters, and may be more likely to conduct biased research as a result. The argument in favor of accepting industry monies is that it is often one of the few, and sometimes the only,

available sources of funding. Our findings suggest that the tobacco industry's credibility is enhanced through its association with independent investigators. The scientists who sit on CIAR's science advisory board, and those who accept funding through its peer-reviewed projects, all provide the tobacco industry with the opportunity to claim that it is funding high-quality, objective research. However, the true purpose of CIAR is made clear by the industry's use of its special-reviewed projects to lobby against regulation of smoking in public places. All researchers associated with CIAR, even those who do not study tobacco-related issues, are contributing to the tobacco industry's agenda.

## Conclusions

CIAR is funding two types of projects for two different purposes. CIAR's peer-reviewed projects are awarded based on the recommendations of independent scientists and most are unrelated to ETS. The tobacco industry may be funding peer-reviewed projects to deflect attention from ETS as an indoor air pollutant, to gain good publicity, and to enhance its credibility. CIAR's special-reviewed projects are awarded based on the recommendations of tobacco industry executives and tend to support the tobacco industry position. The tobacco industry appears to be funding special-reviewed projects to develop scientific data that it can use to lobby against regulation of smoking in public places. CIAR's stated mission of funding high-quality, objective research has been compromised by conflict of interest.

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